



The Keys to Success in  
Sunitinib's Pharmacokinetic  
Bioequivalence Clinical Study  
in Advanced Stage  
Advanced Renal Cell Carcinoma  
/ Gastrointestinal Stromal Tumor:  
A Case Study

Cliantha Research has proven track record in complex patient-based trials. Our in-depth subject knowledge in Oncology studies led to successful completion of Sunitinib's complex clinical trial in the stipulated time. Cliantha's experience & expertise, continuous onsite training & monitoring led to minimum dropouts thereby contributing the maximum number in minimum time.



**Molecule**  
**Indication**

: Sunitinib (Global Pharma)  
: Gastrointestinal Stromal Tumor /  
Advanced Renal Cell Carcinoma

**Phase of the Study**  
**Patients**  
**Sites**

: Pharmacokinetic Bioequivalence Study  
: 46  
: 14



- ⊙ Low number of cases of study Indications (ARCC & GIST)
- ⊙ I/E criteria (age criteria, low Hb level, platelet count etc.)
- ⊙ Pazopanib being the preferred drug of choice
- ⊙ Govt. scheme providing Sunitinib free of cost to patients
- ⊙ Availability of generic sunitinib tablets at lower cost
- ⊙ Major side effects on higher dose of Sunitinib
- ⊙ Patient retention



## CLIANTHA ADVANTAGE

- ⊙ Chose an astute project team with good oncology study experience
- ⊙ Regulatory expertise and knowledge led to early protocol approval
- ⊙ Thorough category experience led to smart selection in
  - ✦ Identification & finalization of experienced and productive investigator sites
  - ✦ Preliminary sample analysis at site for I/E criteria
  - ✦ Selection of subjects non-responding to pazopanib
  - ✦ Patient recruitment based on the weight of the patients to avoid the side effect
- ⊙ Provision of required and methodical training and standardization of PIs and site staff
- ⊙ Efficient management of logistics across central lab & site
- ⊙ On time lab report by Cliantha's central lab beneficial for quick randomization



## CONCLUSION: THE KEYS TO SUCCESS

Experience & strategic planning led to process improvement thereby accelerating the approval & conduct of Sunitinib's complex clinical trial.

To learn more about our clinical research services,  
please visit at **Cliantha.com** or write to us at  
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